RESPONSE TO MERCY HOSPITAL'S WRITTEN COMMENTS IN OPPOSITION TO MAINE MEDICAL CENTERS CERTIFICATE OF NEED APPLICATION TO BUILD AN AMBULATORY SURGICAL FACILITY.

INTRODUCTION:

Contrary to Mercy Hospital's assertions the Certificate of Need Unit (CONU) believes that: (1) There is a public need for the proposed ambulatory surgery facility based on current utilization data provided by Maine Medical Center which shows that services need to be expanded to meet current demand (2) The project meets the objective of the State Health Plan by eliminating threats to patient safety through the reduction of excessive utilization in the Bramhall Operating Rooms (3) Orderly and economic development of health facilities and resources for the State is achieved by relocating the bulk of outpatient surgeries from the crowded, inefficient Bramhall facility to Scarborough, enabling MMC to accommodate the continued shift from inpatient to outpatient surgery 4) The CON application not only provides detailed information regarding the scope of the proposed ambulatory surgical facility but also provides information on MMC's strategic plans, which is over and above the requirements of a CON application. 5) The applicant provided sufficient data to allow the CONU to make its conclusions 6) The existence of funding in the Capital Investment Fund played no part in the CONU decision to approve the project.

The CONU responds to Mercy's comments as follows:

1. No Public Need Exists for the Proposed Additional Surgical Suites

a. The Department has Twice Recently Determined that additional OR's are not Needed in the Portland Area

CONU Response:

These statements are inaccurate. The Commissioner did not attempt to determine the number of operating rooms needed in the Portland area.

Portland Surgery Center

The Portland Surgery Center Application was denied because the applicant did not provide **sufficient evidence** indicating the need for additional OR's in the Portland area.

Mercy Hospital

Mercy Hospitals Phase I Replacement project, which added additional operating room capacity was approved on February 9, 2005.

b. MMC's Application and the Preliminary Staff Report Grossly Overstate MMC's Market for Outpatient Surgery and Its Estimated Volume of Patients.

(1) Contrary to MMC's Representations in its Application, the Relevant Service Area for Outpatient Surgery is, at Most, Cumberland County or the Portland HSA.

CONU Response:

"Hospital service areas" were developed over two decades ago when hospital services were almost entirely inpatient. This definition has not been updated. This measure excludes consideration of tertiary care, newborn care and outpatient admissions that are now a large part of hospital services. In the absence of new data for measuring a hospital's service area CONU is unable to refute MMC's assertions regarding it's primary and secondary service area. There is no data to support Mercy's assertion that outpatient surgery volume is limited to Cumberland County or the Portland hospital service area.

It is Mercy's assertion that MMC is distorting its service area in order to "grossly overstate" its projected volume of patients for its ambulatory surgery center. CONU disagrees. MMC is projecting growth that is slower than its historical average annual growth. No increase in Maine resident's utilization of services is required to support this project. Actual cumulative increases in surgical hours for both inpatient and outpatient services between 1996 and 2003 average 5% per year or 684 new outpatient cases and 134 inpatient cases. MMC projects 400 new outpatient cases and 100 new inpatient cases in their certificate of need application. Mercy did not submit any data refuting MMC's projections.

(2) MMC's Proposed Expansion of its Market for Outpatient Surgery Would Inure to the Disadvantage of Other Hospitals, Patients, and Ultimately the Health Care System.

CONU Response:

Mercy believes that in order to justify a new ambulatory surgery center in Scarborough MMC would have to take market share from Mercy and from providers in outlying areas. CONU disagrees with this assessment based on the utilization data provided by MMC (see above).

(c) MMC is Underutilizing Existing Surgical Services

CONU Response:

Mercy has stated that the existing full service Ambulatory Surgical Center at Brighton is underutilized. Mercy points to an announcement by MMC to its physicians stating, "that there is additional capacity at Brighton. Consider moving your suitable cases to Brighton." MMC's plan is to convert the Brighton Campus Surgical Suite to an

Outpatient Endoscopy Suite. Therefore this is only a temporary situation. According to MMC estimates between 10,500 and 12,000 outpatient endoscopic procedures will be performed at MMC during the forecast period which justifies MMC's conversion. Therefore excess Ambulatory Surgical Capacity would not exist. Mercy submitted no data regarding endoscopy services.

(d) MMC Fails to demonstrate even minimum target utilization rates for its new OR's.

CONU Response:
Mercy states "MMC does not have sufficient volume to meet even the minimum target utilization rate of 80%. MMC forecasts utilization rates of 61% (2007), 73% (2008) and 75% (2009) for its proposed 5 new OR's in Scarborough. MMC calculates total utilization of 80%, 82% and 83% during this same period by combining the average utilization for its 21 operating rooms at its Bramhall Street campus and the proposed 10 operating rooms in Scarborough. Mercy argues that "the methodology MMC proposes (an averaging of its Ors on its two separate campuses) is irrational because similar to their existing ASC proposal, using such reasoning could result in some OR's functioning well below proper utilization and others well above. This would not only be grossly inefficient use of valuable health care resources but would be a distortion of industry and state guidelines" CONU disagrees with this assessment. Mercy states in its application that "their OR utilization plateaus around 64-67% due to their inability to accommodate surgeon and patient demands for block booking time during preferred hours (7am to 3PM) – it should b4e noted that just under 10% of elective hours are between 3-5 pm. Surgeons are very resistant to late blocks of time. Further, when considering an ending time of 3 pm, if a case is expected to take 90 minutes, and last case of the day is scheduled to end at 2, the 90 minute case will not be scheduled thus creating unused capacity at the back end of the day on a regular basis. Mercy has a tight inefficient layout for all services including OR services. The outdated layout of the OR suite itself creates built in inefficiencies that will lower utilization rates of the total capacity." These same scheduling problems and inefficiencies exist at MMC. A major objective of this project is to increase <u>overall</u> OR efficiency. The Bramhall preparation and recovery unit was designed in the early 80's before the massive shift from inpatient to outpatient services. The Bramhall Unit can only handle 15 patients at a time. Given its poor location expansion possibilities are limited. Constructing an ambulatory surgical center in Scarborough would improve traffic and parking while improving access to area patients. This project will eliminate delays and cancellations that result in longer length of stay for inpatients or the need to reschedule outpatients. This would also minimize disruptions to surgeons and staff. Eliminating these inefficiencies would result in the elimination of threats to patient safety, increased OR ability to address emergent and urgent demand and lower cost to the health system.

(e) Ample capacity for Endoscopy Suites Already Exists

CONU Response:

Endoscopy services are not a part of this application so no justification is needed. However, MMC projects 10,500 to 12,000 outpatient endoscopic procedures will be performed during the forecast period of 2007 through 2009. More than 90% of MMC's endoscopic procedures are performed on an outpatient basis by gastroenterologists. MMC's plans to convert the vacated Brighton campus surgical suites to an endoscopy suite are reasonable.

(f) Additional Evidence Negates MMC's Claimed Need for Additional Outpatient Surgical Capacity.

CONU Response:
Mercy's information does not contradict MMC's assertions. The fact that there are other OR's performing specialized surgery (orthopedic, OB/Gyn, Plastic & Hand and eye surgery) does not serve to refute MMC's data. Mercy further claims that MMC's patient data and Cumberland County Patient data are inconsistent, erroneous and unreliable yet they offer none of their own data to support this conclusion.

2. MMC's ASC Project Conflicts with the State Health Plan.

(a) The Bureau of Health Effectively Found that the Proposed ASC is Inconsistent with the State Health Plan.

CONU Response:

The Bureau of Health Assessment did not find that the proposed ASC is inconsistent with the State Health Plan. The Bureau of Health ranked the MMC application for compliance with various criteria specified in the certificate of need rules. There is no conclusion stating that the proposed project conflicts with the State Health Plan.

(b) The MMC Project Duplicates Existing Services or Facilities in a Region that has existing capacity for such services.

MMC's admissions increased from 27,190 in 1996 to 30,800 in 2001, a 13% increase. Statewide admissions increased by 3% (less than population growth). MMC Emergency Department visits increased from 42,000 in 1996 to 52,800 in 2001, a 26% increase. Emergency department visits are projected to increase by 65,000 by 2010. MMC operating rooms are at 90% plus capacity. Constrained access to MMC's surgical services is a patient safety concern. MMC has experienced a 33% increase in surgical cases and a 24% increase in surgical hours from 1996 to 2003. Demand placed on MMC's Bramhall operating rooms exceed the Departments recommended guidelines and industry standards. Current utilization of MMC operating rooms exceeds desirable utilization levels, which reduces the availability of capacity to address emergent and urgent demand. Increases in admissions and emergency room visits will place additional demand on the Bramhall campus operating room capacity to address complex inpatient, emergency and trauma surgery

requirements. Meeting these needs requires additional operating room capacity. CONU believes that this project is necessary to meet an existing demand and is not a duplication of capacity.

(c) The MMC Project Involves a Major Expansion of Existing services or Facilities.

CONU Response:
Please see (b) above. The MMC project is being built to meet an existing demand.

(d) ***The MMC Project Fails to Make the Best Use of Existing Capacity/Infrastructure in Initiatives focused on Expanding Access to Ambulatory or Primary Care Services***.

CONU Response:

Mercy states, "since a full-service ASC already exists at Brighton, prudent health planning would dictate that the best use of the existing capacity/infrastructure would be to add any needed incremental capacity to the existing Brighton space." MMC looked at this alternative. The floor plate of the Brighton facility does not support adding additional operating rooms to the existing ambulatory surgery suite. Adding operating rooms at Brighton would require a small separate surgical suite. This fragmented approach would not achieve the same efficiencies and economies that are possible by developing the service in a contiguous space. Mercy believes that there is no need to increase endoscopy services. "The evidence demonstrates that there is no need, particularly in light of MMC's opening a new Endoscopy Center last month on its Bramhall campus." MMC's application contains data which shows a steady increase in endoscopy services (Please see 1 (e) above). Mercy provides no data which refutes this claim. The demand for less invasive surgeries/diagnostic testing will continue to grow.

(e) The MMC Project Fails to Contribute to Lower Costs of Care and Greater Efficiencies because it Fails to Demonstrate and Appropriate Cost Effective Use for the Abandoned Infrastructure and Contributes to Sprawl.

CONU Response:

MMC clearly states in its application that there will be no abandoned space in either the Brighton or Bramhall Campus. Mercy further states that there is excess space created by the new facility and relies on two independent experts to confirm this. CONU finds it noteworthy that neither independent expert spoke with MMC management to discuss space requirements. CONU believes the experts did not undertake a thorough review of need.

(f) CONU's Conclusion is Based Primarily on items that are Not Related to the Proposed ASC and that will Continue to Exist if the CON is Denied.

Mercy states "The CONU's conclusion that the MMC ASC Application is consistent with the State Health Plan rests on circumstances that have no direct relationship to the proposed new ASC and that will exist regardless of whether the ASC is constructed. That is CONU concluded that the proposed ASC is consistent with the State Health Plan because (i) MMC has implemented the Chronic Care Model (ii) MMC has complied with the Governor's request to restrain cost increases and (iii) MMC has met the computerized standard of the Leap Frog Group. The CONU concluded that the project meets the objective of the State Health Plan because the project eliminates threats to patient safety by eliminating excessive utilization that exceeds Department guidelines and industry standards. Items i, ii, and iii above are elements of the State Health Plan that must be evaluated by CONU.

3. MMC's Project is Inconsistent with the Orderly and Economic Development of Health Facilities and Health Resources for the State.

(a) ***The MMC ASC Project Would Have a Direct Negative Impact on Mercy Hospital and other Providers.***

Impact of Volume Shift – OR Expansion

CONU Response:
CONU concluded that the proposed increase in OR capacity is a response to an existing demand and necessary to improve efficiency and safety. MMC's volume projections are very conservative and would occur whether or not the project is completed. Mercy's data is speculative and based on an extremely limited service area.

Impact of Volume Shift –Endoscopy Expansion

CONU Response:
Mercy states, "that in order to achieve the proper utilization needed to support the proposed additions, significant volume must shift from existing providers to MMC. These patients will come from Mercy Hospital, as well as from other market endoscopy centers" Mercy did not provide any data contradicting MMC's volume projections of 10,500 to 12,000 outpatient endoscopy during the forecast period (2007 –2009). In Mercy's CON application they stated that outpatient surgery volumes have increased by 58% and outpatient diagnostic imaging volumes have increased by 48% since 1997. This growth is representative of broader trends affecting hospitals.

. Continued shift from inpatient to outpatient settings for surgery with specific increases in minimally invasive surgery.
. Improved technology which speeds postoperative healing.
. Technology advancements that have improved diagnostic capabilities in imaging.
. Minimally invasive procedures increasing the demand for imaging services.

Impact on Mercy if MMC Expands Facility in the Future

CONU Response:
Mercy expressed concern about the construction of the 56,500 square foot Ambulatory Surgery Center which they consider unnecessary for the proposed services. They feel that excess space (estimated at approximately 20,000 sq. feet by two outside consultants) will be used for undisclosed future expansion. A review of the proposed floor plan indicates that the facility is organized as follows:

Basement: Central Sterile Processing, Materials Management, Clinical Engineering, Environmental Service and Materials.

1st Floor: Surgical Suite, Pre-Operative Preparation, Short-Term and 23 Hour Recovery and Public Functions.

The facility includes ten operating rooms, 25 recovery beds and a separate 6 bed, 23-hour recovery area for patients needing accommodation for an extended recovery period. CONU has reviewed the work of the two outside consultants (Surgery Management Improvement Group, Inc. and the KLMK Group). Both consultants conclude that after a review of the **"report"** the floor plan should only be 35,000 to 37,500 sq. feet. The consultants did not mention a review of the floor plan or specifically mention which areas should be eliminated or modified. No sources were sited besides "consultant experience" in determining square footage. CONU's review of the floor plans shows no unused or "shell space". As stated earlier CONU feels that the experts did not conduct a thorough review.

(b) Viable Less Costly Alternatives are Available

Brighton Full Service Ambulatory Surgery Center

CONU Response:
Mercy states "Because both MMC's Bramhall and Brighton campuses already offer ambulatory surgical services, the question arises as to why neither of these facilities would be modified to provide additional surgical capacity in the Portland area" Consolidating ambulatory surgical facilities at the Brighton Unit would not offer the efficiencies of developing the service in a contiguous space.

Vacated Space on the Bramhall Campus

CONU Response:
Mercy contends that as a result of the new $62.7 million four-story facility for obstetrical and newborn/neonatal services on the Bramhall campus. 28,000 square feet of space was vacated in the Bean building and 14,000 square feet was vacated in the Richards building. MMC states in its application "Increasing operating room capacity in proximity to the existing Bramhall Surgical Services department is

extremely difficult. There is no vacant space on the Bramhall campus, let alone in proximity to the surgical suite. Such a project would involve significant dislocation of other functions. Attempts to maintain current volume of ambulatory surgery at the Bramhall campus would require a major expansion of the Preparation and Recovery Unit as well, which would further exacerbate the dislocation of other functions. Increasing capacity on the Bramhall campus does not improve access to surgical services for emergent and urgent patients in the same manner as the off-site alternative, since substantial outpatient surgery would continue to be scheduled in the Bramhall operating rooms. This approach does not alleviate the traffic and congestion on the main campus, which is an ongoing concern.

(c) MMC's Project Fails to Maximize Capacity of Current Resources

CONU Response

CONU disagrees. As an urban hospital located in the heart of Portland, MMC faces many challenges. The current Bramhall facility was designed in the 1980's before the massive shift from inpatient to outpatient services. Expansion potential is costly and impractical. The Brighton campus is being utilized for other services and would not create the efficiencies that the Scarborough location would.

(d) MMC's Project Contributes to Sprawl and Fails to Demonstrate an Appropriate Cost Effective Use for Abandoned Infrastructure.

CONU Response:
MMC faces the same problems as Mercy who states in their Phase I Replacement CON Application "In addition to being too small to house all functions, Mercy's current facilities do not afford space that fully accommodates efficient and high quality care patterns and practices. Too limited space, inefficient adjacencies and undersized infrastructure create inefficiencies and inconvenient for patients, visitors and staff. Mercy has been facing these space constraints and related issues for some time. Previous efforts to address the problems within the current campus and facility footprint have come to an unsuccessful conclusion due to site limitations." There is no abandoned infrastructure and the Bramhall and Brighton campus are simply not the best alternative for ambulatory surgical services.

4. The CON Application Substantially Underrepresents the Scope of Expansion of Both Facilities and Capacity that would Result from the Proposed Project(s).

CONU Response:
Mercy states "the MMC application focuses primarily on the development of its proposed new ASC services in Scarborough. The application provides little information - and essentially no information to determine capital or operating costs – as to the other expansions of both facility and capacity that are elements of this proposed project. Accordingly, the application should be denied simply on the basis of the applicant's failure to disclose essential data from which the Department can

accurately assess the need, cost and overall impact of all of the expansions of the facility and capacity that would result from approval of the project." MMC states in its application that costs to build the endoscopy suite at Brighton campus are "minimal". If this is under the requirements for a Certificate of Need and not otherwise subject to review, they are not required to disclose it. CONU is unaware of any plans to develop 4 new inpatient operating rooms at Bramhall.

5. Miscellaneous Deficiencies in the MMC Application.

(a) MMC Fails to Reveal the Cost of its Proposed Project.

CONU Response:
The cost of the project is $27,306,000. MMC already owns the land. The costs of retrofitting Brighton are "minimal" (see above). The consultant hired by Mercy relied on "consultant experience" to determine staffing levels. They did not discuss this with MMC staff.

(b) MMC Does not Provide the Required Financial Pro Formas and Third Party Financial Feasibility Opinion.

CONU Response:

MMC did not provide a third party financial feasibility opinion because they are paying for the entire project in **cash**. They have ample cash and investments on their balance sheet to do this. MMC did provide pro forma financial data.

(c)The Application Proposes an Excessively Overbuilt Facility for One of the Proposed Services.

As stated above CONU disagrees with this assessment. We believe that the experts did not conduct a thorough review of the proposed facility. They did not speak with MMC staff or review the proposed floor plans.

(d) MMC Has not Obtained Municipal Site Approval for its Proposed Site.

CONU Response:

MMC is currently seeking approval for the project. Should additional costs arise due to unanticipated cost overruns the project will be subject to subsequent review. In addition the Commissioner can make site approval a condition of the project at his discretion.

6. The Mere Existence of a Sufficient Cap Within the Capital Investment Fund Does not Justify CON Approval.

CONU Response:

Mercy states – “The availability of a sufficient cap in the Capital Investment Fund, 22 MRSA Section 335(7), does not justify the Department’s approval of all projects submitted for CON approval in a particular review cycle”. CONU agrees with this statement. All projects are approved or disapproved based on the merits of the project.